

[Federal Register: March 2, 2009 (Volume 74, Number 39)]
[Proposed Rules]
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[DOCID:fr02mr09-7]

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EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1635

RIN 3046-AA84

Regulations Under the Genetic Information Nondiscrimination Act
of 2008

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

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List of Subjects in 29 CFR Part 1635

Administrative practice and procedure, Equal employment
opportunity.

For the reasons set forth in the preamble, the EEOC proposes to
amend 29 CFR chapter XIV by adding part 1635 to read as follows:

PART 1635--GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

Sec.

- 1635.1 Purpose.
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- 1635.11 Construction.
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Authority: 110 Stat. 233; 42 U.S.C. 2000ff.

Sec. 1635.1 Purpose.

The purpose of this part is to implement Title II of the Genetic
Information Non-Discrimination Act of 2008, 42 U.S.C. 2000ff, et seq.
Title II of GINA prohibits use of genetic information in employment

decision-making, restricts deliberate acquisition of genetic information, requires that genetic information be maintained as a confidential medical record, and places strict limits on disclosure of genetic information. The law provides remedies for individuals whose genetic information is acquired, used, or disclosed in violation of its protections.

Sec. 1635.2 Definitions--general.

(a) Commission means the Equal Employment Opportunity Commission, as established by section 705 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-4.

(b) Covered Entity means an employer, employing office, employment agency, labor organization, or joint labor-management committee.

(c) Employee means an individual employed by a covered entity, as well as an applicant for employment and a former employee. An employee, including an applicant for employment and a former employee, is

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(1) As defined by section 701 of the Civil Rights Act of 1964, 42 U.S.C. 2000e, an individual employed by a person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year and any agent of such a person;

(2) As defined by section 304(a) of the Government Employee Rights Act, 42 U.S.C. 2000e-16c(a), a person chosen or appointed by an individual elected to public office by a State or political subdivision of a State to serve as part of the personal staff of the elected official, to serve the elected official on a policy-making level, or to serve the elected official as the immediate advisor on the exercise of the elected official's constitutional or legal powers.

(3) As defined by section 101 of the Congressional Accountability Act, 2 U.S.C. 1301, any employee of the House of Representatives, the Senate, the Capitol Guide Service, the Capitol Police, the Congressional Budget Office, the Office of the Architect of the Capitol, the Office of the Attending Physician, the Office of Compliance, or the Office of Technology Assessment;

(4) As defined by, and subject to the limitations in, section 2(a) of the Presidential and Executive Office Accountability Act, 3 U.S.C. 411(c), any employee of the executive branch not otherwise covered by section 717 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-16, section 15 of the Age Discrimination in Employment Act of 1967, 29 U.S.C. 633a, or section 501 of the Rehabilitation Act of 1973, 29 U.S.C. 791, whether appointed by the President or any other appointing authority in the executive branch, including an employee of the Executive Office of the President;

(5) As defined by, and subject to the limitations in, section 717 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-16, and regulations of the Equal Employment Opportunity Commission at 29 CFR 1614.103, an employee of a federal executive agency, the United States Postal Service and the Postal Rate Commission, the Tennessee Valley Authority, the National Oceanic and Atmospheric Administration Commissioned Corps, the Government Printing Office, and the Smithsonian Institution; an employee of the federal judicial branch having a position in the competitive service; and an employee of the Library of Congress.

(d) Employer means any person that employs an employee defined in Sec. 1635.2(c) of this part, and any agent of such person, except that, as limited by section 701(b)(1) and (2) of the Civil Rights Act of 1964, 42 U.S.C. 2000e(b)(1) and (2), an employer does not include an Indian tribe or a bona fide private club (other than a labor organization) that is exempt from taxation under section 501(c) of the Internal Revenue Code of 1986.

(e) Employing office is defined in the Congressional Accountability Act, 2 U.S.C. 1301(9), to mean the personal office of a Member of the House of Representatives or of a Senator; a committee of the House of Representatives or the Senate or a joint committee; any other office headed by a person with the final authority to appoint, hire, discharge, and set the terms, conditions, or privileges of the employment of an employee of the House of Representatives or the Senate; or the Capitol Guide Board, the Capitol Police Board, the Congressional Budget Office, the Office of the Architect of the Capitol, the Office of the Attending Physician, the Office of Compliance, and the Office of Technology Assessment.

(f) Employment agency is defined in 42 U.S.C. 2000e(c) to mean any person regularly undertaking with or without compensation to procure employees for an employer or to procure for employees opportunities to work for an employer and includes an agent of such a person.

(g) Joint labor-management committee is defined as an entity that controls apprenticeship or other training or retraining programs, including on-the-job training programs.

(h) Labor organization is defined at 42 U.S.C. 2000e(d) to mean an organization with fifteen or more members engaged in an industry affecting commerce, and any agent of such an organization in which employees participate and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or conditions of employment.

(i) Member includes, with respect to a labor organization, an applicant for membership.

(j) Person is defined at 42 U.S.C. 2000e(a) to mean one or more individuals, governments, governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, trustees, trustees in cases under title 11, or receivers.

(k) State is defined at 42 U.S.C. 2000e(i) and includes a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, and Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.).

Sec. 1635.3 Definitions specific to GINA.

(a) Family member means with respect to any individual

(1) A person who is a dependent of that individual as the result of marriage, birth, adoption, or placement for adoption; or

(2) A first-degree, second-degree, third-degree, or fourth-degree relative of the individual, or of a dependent of the individual as defined in Sec. 1635.3(a)(1).

(i) First-degree relatives include an individual's parents, siblings, children, and half-siblings.

(ii) Second-degree relatives include an individual's grandparents,

grandchildren, uncles, aunts, nephews, and nieces.

(iii) Third-degree relatives include an individual's great-grandparents, great grandchildren, great uncles/aunts, and first cousins.

(iv) Fourth-degree relatives include an individual's great-great grandparents, great-great grandchildren, and first cousins once-removed (i.e., the children of the individual's first cousins).

(b) Family medical history. Family medical history means information about the manifestation of disease or disorder in family members of the individual.

(c) Genetic information. (1) Genetic information means information about:

(i) An individual's genetic tests;

(ii) The genetic tests of that individual's family members;

(iii) The manifestation of disease or disorder in family members of the individual (family medical history);

(iv) An individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or

(v) The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.

(2) Genetic information does not include information about the sex or age of the individual or the sex or age of family members.

(d) Genetic monitoring means the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, caused by the toxic substances they use or are exposed

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to in performing their jobs, in order to identify, evaluate, and respond to the effects of or control adverse environmental exposures in the workplace.

(e) Genetic services means a genetic test; genetic counseling (including obtaining, interpreting, or assessing genetic information); or genetic education.

(f) Genetic test--(1) In general. ``Genetic test'' means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.

(i) An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes is not a genetic test.

(ii) A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites is not a genetic test.

(2) Alcohol and drug testing. (i) A test for the presence of alcohol or drugs is not a genetic test.

(ii) A test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.

(g) Manifestation or manifested means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this part, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information

or on the results of one or more genetic tests.

Sec. 1635.4 Prohibited practices--in general.

(a) It is unlawful for an employer to discriminate against an individual on the basis of the genetic information of the individual in regard to hiring, discharge, compensation, terms, conditions, or privileges of employment.

(b) It is unlawful for an employment agency to fail or refuse to refer any individual for employment or otherwise discriminate against any individual because of genetic information of the individual.

(c) It is unlawful for a labor organization to exclude or to expel from the membership of the organization, or otherwise to discriminate against, any member because of genetic information with respect to the member.

(d) It is an unlawful employment practice for any employer, labor organization, or joint labor-management committee controlling apprenticeship or other training or retraining programs, including on-the-job training programs to discriminate against any individual because of the individual's genetic information in admission to, or employment in, any program established to provide apprenticeship or other training or retraining.

Sec. 1635.5 Limiting, segregating, and classifying.

(a) A covered entity may not limit, segregate, or classify an individual, or fail or refuse to refer for employment any individual, in any way that would deprive or tend to deprive the individual of employment opportunities or otherwise affect the status of the individual as an employee, because of genetic information with respect to the individual.

(b) Notwithstanding any language in this part, a cause of action for disparate impact within the meaning of section 703(k) of the Civil Rights Act of 1964, 42 U.S.C. 2000e-2(k), is not available under this part.

Sec. 1635.6 Causing an employer to discriminate.

An employment agency, labor organization, or joint labor-management training or apprenticeship program may not cause or attempt to cause an employer, or its agent, to discriminate against an individual in violation of this part, including with respect to the individual's participation in an apprenticeship or other training or retraining program, or with respect to a member's participation in a labor organization.

Sec. 1635.7 Retaliation.

A covered entity may not discriminate against any individual because such individual has opposed any act or practice made unlawful by this title or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this title.

Sec. 1635.8 Acquisition of genetic information.

(a) General prohibition. A covered entity may not request, require, or purchase genetic information of an individual, except as specifically provided in paragraph (b) of this section.

(b) Exceptions. The general prohibition against requesting, requiring, or purchasing genetic information does not apply:

(1) Where a covered entity inadvertently requests or requires genetic information of the individual or family member of the individual. This exception to the acquisition of genetic information applies in, but is not necessarily limited to, situations where--

(i) A manager, supervisor, union representative, or employment agency personnel learns genetic information about an individual by overhearing a conversation between the individual and others;

(ii) A manager, supervisor, union representative, or employment agency personnel learns genetic information about an individual by receiving it from the individual or third-parties without having solicited or sought the information;

(iii) An individual provides genetic information as part of documentation to support a request for reasonable accommodation under Federal, State, or local law, as long as the covered entity's request for such documentation is lawful;

(iv) An employer requests medical information (other than genetic information) as permitted by Federal, State, or local law from an individual, who responds by providing, among other information, genetic information;

(v) An individual provides genetic information to support a request for leave that is not governed by Federal, State, or local laws requiring leave, as long as the documentation required to support the request otherwise complies with the requirements of the Americans with Disabilities Act and other laws limiting a covered entity's access to medical information; or

(vi) A covered entity learns genetic information about an individual in response to an inquiry about the individual's general health, an inquiry about whether the individual has any current disease, disorder, or pathological condition, or an inquiry about the general health of an individual's family member;

(2) Where a covered entity offers health or genetic services, including such services offered as part of a voluntary wellness program. This exception applies only where--

(i) The individual provides prior knowing, voluntary, and written authorization that

(A) Is written so that the individual from whom the genetic information is being obtained is reasonably likely to understand the form;

(B) Describes the type of genetic information that will be obtained and the general purposes for which it will be used; and

(C) Describes the restrictions on disclosure of genetic information.

(ii) Individually identifiable genetic information is provided only to the

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individual (or family member if the family member is receiving genetic

services) and the licensed health care professional or board certified genetic counselor involved in providing such services; and

(iii) Any individually identifiable genetic information provided under paragraph (b)(2) of this section is only available for purposes of such services and is not disclosed to the covered entity except in aggregate terms that do not disclose the identity of specific individuals.

(3) Where the employer requests family medical history to comply with the certification provisions of the Family and Medical Leave Act of 1993 (29 U.S.C. 2601 et seq.) or State or local family and medical leave laws.

(4) Where the covered entity acquires genetic information from documents that are commercially and publicly available for review or purchase, including newspapers, magazines, periodicals, or books, or through electronic media, such as information communicated through television, movies, or the Internet, except that a covered entity may not research medical databases or court records, even where such databases may be publicly and commercially available, for the purpose of obtaining genetic information about an individual.

(5) Where the covered entity acquires genetic information for use in the genetic monitoring of the biological effects of toxic substances in the workplace. In order for this exception to apply, the covered entity must provide written notice of the monitoring to the individual. This exception further provides that such monitoring:

(i) Either is required by federal or state law, or conducted only where an individual gives prior knowing, voluntary and written authorization to the monitoring that--

(A) Is written so that the individual from whom the genetic information is being obtained is reasonably likely to understand the form.;

(B) Describes the genetic information that will be obtained;

(C) Describes the restrictions on disclosure of genetic information;

(ii) Ensures that the individual is informed of individual monitoring results;

(iii) Is conducted in compliance with any Federal genetic monitoring regulations, including any regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.); and

(iv) Provides for reporting of the results of the monitoring to the covered entity, excluding any licensed health care professional or board certified genetic counselor involved in the genetic monitoring program, only in aggregate terms that do not disclose the identity of specific individuals.

(6) Where an employer that conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification requests or requires genetic information of its employees, apprentices, or trainees, but only to the extent that the genetic information is used for analysis of DNA identification markers for quality control to detect sample contamination and maintained in a manner consistent with such use.

(c) A covered entity may not use genetic information obtained

pursuant to the exceptions in Sec. 1635.8(b) of this part to discriminate, as defined by Sec. Sec. 1635.4, 1635.5, or 1635.6, and must keep such information confidential as required by Sec. 1635.9.

Sec. 1635.9 Confidentiality.

(a) Treatment of genetic information. (1) A covered entity that possesses genetic information in writing about an employee or member must maintain such information on forms and in medical files (including where the information exists in electronic forms and files) that are separate from personnel files and treat such information as a confidential medical record.

(2) A covered entity may maintain genetic information about an employee or member in the same file in which it maintains confidential medical information subject to section 102(d)(3)(B) of the Americans with Disabilities Act, 42 U.S.C. 12112(d)(3)(B).

(3) Genetic information that a covered entity receives orally need not be reduced to writing, but may not be disclosed, except as permitted by this part.

(4) Genetic information that a covered entity acquires through publicly available sources, as provided by Sec. 1635.8(b)(4) of this part, is not considered confidential genetic information, but may not be used to discriminate against an individual as described in Sec. Sec. 1635.4, 1635.5, or 1635.6 of this part.

(b) Limitations on disclosure. A covered entity that possesses any genetic information, regardless of how the entity obtained the information (except for genetic information acquired through publicly available sources), may not disclose it except:

(1) To the employee or member (or family member if the family member is receiving the genetic services) about whom the information pertains upon receipt of the employee's or member's written request;

(2) To an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under 45 CFR part 46;

(3) In response to an order of a court, except that the covered entity may disclose only the genetic information expressly authorized by such order; and if the court order was secured without the knowledge of the individual to whom the information refers, the covered entity shall inform the individual of the court order and any genetic information that was disclosed pursuant to such order;

(4) To government officials investigating compliance with this title if the information is relevant to the investigation;

(5) To the extent that such disclosure is made in support of an employee's compliance with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws; or

(6) To a Federal, State, or local public health agency only with regard to information about the manifestation of a disease or disorder that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness, provided that the individual whose family member is the subject of the disclosure is notified of such disclosure.

(c) Relationship to HIPAA Privacy Regulations. Pursuant to Sec. 1635.11(d) of this part, nothing in this section shall be construed as applying to the use or disclosure of genetic information that is protected health information subject to the regulations issued pursuant

to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

Sec. 1635.10 Enforcement and Remedies.

(a) Powers and procedures: The following powers and procedures shall apply to allegations that Title II of GINA has been violated:

(1) The powers and procedures provided to the Commission, the

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Attorney General, or any person by sections 705 through 707 and 709 through 711 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-4 through 2000e-6 and 2000e-8 through 2000e-10, where the alleged discrimination is against an employee defined in 1635.2(c)(1) of this part or against a member of a labor organization;

(2) The powers and procedures provided to the Commission and any person by sections 302 and 304 of the Government Employees Rights Act, 42 U.S.C. 2000e-16b and 2000e-16c, and in regulations at 29 CFR part 1603, where the alleged discrimination is against an employee as defined in Sec. 1635.2(c)(2) of this part;

(3) The powers and procedures provided to the Board of Directors of the Office of Compliance and to any person under the Congressional Accountability Act, 2 U.S.C. 1301 et seq. (including the provisions of Title 3 of that act, 2 U.S.C. 1381 et seq.), where the alleged discrimination is against an employee defined in Sec. 1635.2(c)(3) of this part;

(4) The powers and procedures provided in 3 U.S.C. 451 et seq., to the President, the Commission, or any person in connection with an alleged violation of section 3 U.S.C. 411(a)(1), where the alleged discrimination is against an employee defined in Sec. 1635.2(c)(4) of this part;

(5) The powers and procedures provided to the Commission, the Librarian of Congress, and any person by section 717 of the Civil Rights Act, 42 U.S.C. 2000e-16, where the alleged discrimination is against an employee defined in Sec. 1635.2(c)(5) of this part.

(b) Remedies. The following remedies are available for violations of GINA sections 202, 203, 204, 205, 206, and 207(f):

(1) Compensatory and punitive damages as provided for, and limited by, 42 U.S.C. 1981a(a)(1) and (b);

(2) Reasonable attorney's fees, including expert fees, as provided for, and limited by, 42 U.S.C. 1988(b) and (c); and

(3) Injunctive relief, including reinstatement and hiring, back pay, and other equitable remedies as provided for, and limited by, 42 U.S.C. 2000e-5(g).

Sec. 1635.11 Construction.

(a) Relationship to other laws, generally. This part does not--

(1) Limit the rights or protections of an individual under any other Federal, State, or local law that provides equal or greater protection to an individual than the rights or protections provided for under this part, including the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.), and State and local laws prohibiting genetic

discrimination or discrimination on the basis of disability;

(2) Apply to the Armed Forces Repository of Specimen Samples for the Identification of Remains;

(3) Limit or expand the protections, rights, or obligations of employees or employers under applicable workers' compensation laws;

(4) Limit the authority of a Federal department or agency to conduct or sponsor occupational or other health research in compliance with the regulations and protections provided for under 45 CFR part 46;

(5) Limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration to promulgate or enforce workplace safety and health laws and regulations; or

(6) Require any specific benefit for an employee or member or a family member of an employee or member (such as additional coverage for a particular health condition that may have a genetic basis) under any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan.

(b) Relation to certain Federal laws governing health coverage.

Nothing in GINA Title II provides for enforcement of, or penalties for, violation of any requirement or prohibition of a covered entity subject to enforcement for a violation of:

(1) Amendments made by Title I of GINA.

(2) Section 701(a) of the Employee Retirement Income Security Act (29 U.S.C. 1181) (ERISA), section 2701(a) of the Public Health Service Act (42 U.S.C. 300gg(a)), and section 9801(a) of the Internal Revenue Code (26 U.S.C. 9801(a)), as such sections apply with respect to genetic information pursuant to 29 U.S.C. 1181(b)(1)(B), 42 U.S.C. 300gg(b)(1)(B), and 26 U.S.C. 9801(b)(1)(B), respectively, of such sections, which prohibit a group health plan or a health insurance issuer in the group market from imposing a preexisting condition exclusion based solely on genetic information, in the absence of a diagnosis of a condition;

(3) Section 702(a)(1)(F) of ERISA (29 U.S.C. 1182(a)(1)(F)), section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg-1(a)(1)(F)), and section 9802(a)(1)(F) of the Internal Revenue Code (26 U.S.C. 9802(a)(1)(F)), which prohibit a group health plan or a health insurance issuer in the group market from discriminating against individuals in eligibility and continued eligibility for benefits based on genetic information; or

(4) Section 702(b)(1) of ERISA (29 U.S.C. 1182(b)(1)), section 2702(b)(1) of the Public Health Service Act (42 U.S.C. 300gg-1(b)(1)), and section 9802(b)(1) of the Internal Revenue Code (26 U.S.C. 9802(b)(1)), as such sections apply with respect to genetic information as a health status-related factor, which prohibit a group health plan or a health insurance issuer in the group market from discriminating against individuals in premium or contribution rates under the plan or coverage based on genetic information.

(c) Relationship to authorities under GINA Title I. GINA Title II does not prohibit any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan from engaging in any action that is authorized under any provision of law noted in Sec. 1635.11(b) of this part, including any implementing regulations noted in Sec. 1635.11(b).

(d) Relationship to HIPAA Privacy Regulations. This part does not apply to genetic information that is protected health information subject to the regulations issued by the Secretary of Health and Human Services pursuant to section 264(c) of the Health Insurance Portability

and Accountability Act of 1996.

Sec. 1635.12 Medical information that is not genetic information.

(a) Medical information about a manifested disease, disorder, or pathological condition. (1) A covered entity shall not be considered to be in violation of this part based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, even if the disease, disorder, or pathological condition has or may have a genetic basis or component.

(2) Notwithstanding paragraph (a)(1) of this section, the acquisition, use, and disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition is subject to applicable limitations under sections 103(d)(1)-(4) of the Americans with Disabilities Act (42 U.S.C. 12112(d)(1)-(4)), and regulations at 29 CFR 1630.13, 1630.14, and 1630.16.

(b) Genetic information related to a manifested disease, disorder, or pathological condition. Notwithstanding paragraph (a) of this section, genetic information about a manifested disease, disorder, or

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pathological condition is subject to the requirements and prohibitions in sections 202 through 206 of GINA and Sec. Sec. 1635.4 through 1635.7 and 1635.9 of this part.

[FR Doc. E9-4221 Filed 2-27-09; 8:45 am]

BILLING CODE 6570-01-P